

REMARKS

Applicants have amended their claims in order to further clarify the definition of various aspects of the present invention. Specifically, Applicants have amended claim 1 to recite the step of adding (a) an anti-interleukin 10 (IL-10) antibody and (b) a stimulus which induces cell-mediated immunological reaction against *Mycobacterium avium* subsp. *paratuberculosis* in the collected blood, to the collected blood, so as to induce the cell-mediated immunological reaction. Applicants have amended claim 4 in light of amendments to claim 1, to recite that the stimulus added to the collected blood is selected from a specified group, this group including soluble antigen obtained by sterilizing *Mycobacterium avium* subsp. *paratuberculosis* with heat to break the bacterial cells and collecting the supernatant. In connection with amendment of claim 4, note, for example, the last full paragraph on page 17 of Applicants' English-language specification submitted April 26, 2007 (hereinafter "Applicants' specification").

In addition, in order to simplify issues, Applicants have cancelled claims 3 and 5-10 without prejudice or disclaimer.

Moreover, Applicants are adding new claims 11-13 to the application. Claim 11, dependent on claim 1, recites that the stimulus added to the collected blood is a *Mycobacterium avium* subsp. *paratuberculosis* antigen. Claims 12 and 13, dependent respectively on claims 11 and 1, recite that culturing is performed between the adding and the measuring as in the parent claims. Note, for example, original claim 1.

The rejection of claims 1-3, 5 and 6 under the second paragraph of 35 USC 112, "as being incomplete for omitting essential elements", set forth in Item 6 on page 3 of the Office Action mailed January 29, 2009, is noted. Applicants

have amended claim 1 to recite that in addition to an anti-interleukin 10 (IL-10) antibody added to the collected blood, a stimulus which induces cell-mediated immunological reaction against *Mycobacterium avium* subsp. *paratuberculosis* in the collected blood, is also added to the collected blood, so as to induce the cell-mediated immunological reaction. Thus, claim 1 has been amended to recite what the Examiner characterizes as the “missing element” in Item 6 on page 3 of the Office Action mailed January 29, 2009, that is, “the stimulus which induces said CMI reaction”. In view of this amendment of claim 1, it is respectfully submitted that the rejection of claims 1 and 2 under 35 USC 112, second paragraph, as being incomplete, is moot. As claims 3, 5 and 6 have been cancelled, the rejection thereof in Item 6 on page 3 of the Office Action mailed January 29, 2009, is moot.

The rejections of claims 7-10 under the second paragraph of 35 USC 112, as being indefinite, set forth in Items 7 and 8 on pages 3 and 4 of the Office Action mailed January 29, 2009, are noted. Such rejections are moot in light of cancelling of claims 7-10 without prejudice or disclaimer.

The rejection of claim 4 under the second paragraph of 35 USC 112, as being indefinite, in Item 9 on page 4 of the Office Action mailed January 29, 2009, the Examiner contending that it is unclear what is meant by antigen obtained “by” heat-killing the bacterium, is noted. Claim 4 has been amended consistent with description in Applicants’ specification, to recite a soluble antigen obtained by sterilizing *Mycobacterium avium* subsp. *paratuberculosis* with heat to break the bacterial cells and collecting the supernatant. It is respectfully submitted that claim 4 as presently amended, in connection with the recited soluble antigen, is sufficiently definite so as to satisfy requirements of the second paragraph of 35 USC 112.

May 29, 2009

In view of the foregoing comments and amendments, reconsideration and allowance of all claims in the above-identified application are respectfully requested.

To the extent necessary, Applicants hereby petition for an extension of time under 37 CFR 1.136. Kindly charge any shortage of fees due in connection with the filing of this paper, including any extension of time fees, to the Deposit Account of Antonelli, Terry, Stout & Kraus, LLP, Account No. 01-2135 (case 1333.46042X00), and please credit any overpayments to such Deposit Account.

Respectfully submitted,

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